is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of §820.180, with respect to the general requirements concerning records, and §820.198, with respect to complaint files.

[54 FR 47206, Nov. 13, 1989]

§ 864.3300 Cytocentrifuge.

(a) *Identification.* A cytocentrifuge is a centrifuge used to concentrate cells from biological cell suspensions (e.g., cerebrospinal fluid) and to deposit these cells on a glass microscope slide for cytological examination.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 60588, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989]

§ 864.3400 Device for sealing microsections.

(a) *Identification.* A device for sealing microsections is an automated instrument used to seal stained cells and microsections for histological and cytological examination.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 60589, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989]

§ 864.3600 Microscopes and accessories.

(a) *Identification.* Microscopes and accessories are optical instruments used to enlarge images of specimens, preparations, and cultures for medical purposes. Variations of microscopes and accessories (through a change in the light source) used for medical purposes include the following:

(1) Phase contrast microscopes, which permit visualization of unstained preparations by altering the phase relationship of light that passes around the object and through the object.

(2) Fluorescense microscopes, which permit examination of specimens stained with fluorochromes that fluoresce under ultraviolet light.

(3) Inverted stage microscopes, which permit examination of tissue cultures or other biological specimens contained in bottles or tubes with the light source mounted above the specimen.

(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The devices are also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.

[45 FR 60590, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989]

§ 864.3800 Automated slide stainer.

(a) *Identification.* An automated slide stainer is a device used to stain histology, cytology, and hematology slides for diagnosis.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 60591, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989]

§ 864.3875 Automated tissue processor.

(a) *Identification.* An automated tissue processor is an automated system used to process tissue specimens for examination through fixation, dehydration, and infiltration.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 60591, Sept. 12, 1980, as amended at 54 FR 25045, June 12, 1989]

Subpart E—Specimen Preparation Reagents

§ 864.4010 General purpose reagent.

(a) A general purpose reagent is a chemical reagent that has general laboratory application, that is used to collect, prepare, and examine specimens from the human body for diagnostic